22. The milling apparatus according to claim 21, wherein the angle between the rotation axis and the longitudinal axis is approximately 96 degrees.

23. The milling apparatus according to claim 18, wherein the rotary form cutter is provided with a gear surface and the drive is provided with a gear at the distal end, and wherein the drive is coupled to the rotary form cutter by intermeshing the gear surface with the gear.

24. The milling apparatus according to claim 18, wherein the predetermined shape is a concaval-convex shape.

REMARKS

Claims 1 through 24 are pending in the present application. By this Amendment, the specification has been amended to cure a noted discrepancy between the specification and drawings. Claim 1 has been amended to more clearly define the present invention. In addition, the dependency of claim 10 has been amended to cure a noticed problem with antecedents for the term "the belt". Further, claims 18 through 24 have been added to further define the present invention. No new matter is believed to be presented by these amendments.

Claim Rejections - 35 U.S.C. §102

Claims 1, 2, 4, 5 and 7 were rejected under 35 U.S.C. §102(b) as being anticipated by Noiles (U.S. Patent No. 4,662,891). The Office Action asserts that Noiles discloses a concave form cutter 10, which meets the requirements of the rejected claims. The Applicants respectfully traverse this rejection for the following reasons.

Noiles teaches a fixation element 10, as shown in Figure 4, that includes a self-tapping thread 18 and a set of cutting teeth 50 and are interposed between a spherical dome 54 and the self-tapping thread 18. As shown in Figure 3, the fixation element 10 is screwed into a cavity 46 of a bone in which the socket in an artificial ball and socket join has been reamed using a spherical reamer 42 as shown in Figure 2. Thus, contrary to the assertions in the Office Action, the fixation element 10 is not a form cutting device. Rather, the spherical reamer 42, as shown in Figure 2, is actually used for reaming a conical cavity into the cotyloid cavity 1 in the bones comprising the pelvis of a human.

In contrast, the present invention includes a drill head having a profile capable of imparting a shape to the bone of opposing vertebral bodies. Noiles does not teach or suggest that the spherical reamer 42 is capable of imparting the shape to the bone of opposing vertebral bodies. Rather, the spherical reamer 42 is clearly taught for use with pelvic bones to form the socket portion of a ball and socket joint. Hence, Noiles cannot be relied upon as teaching all the elements of the claimed invention.

Furthermore, the Office Action asserts that "the intended use of the claimed device has been considered but does not serve to structurally distinguish the claim over the applied reference". The Applicants assume that the "intended use" referred to is the claimed profile of the form cutter being of a height capable of being admitted into the space between the two opposing vertebral bodies. However, the Applicants respectfully, but strongly, disagree with this assertion since this element of the claim further defines the structure of the form cutter such that its structure affords admission into the space between the opposing vertebral bodies. Noiles does not teach or suggest that the spherical reamer 42 has a profile structure such that it could be

inserted between opposing vertebrae. Indeed, Noiles teaches a specific use of the spherical reamer 42 with the pelvic bones through a limited angle of use, indicated by α in Figure 2. Thus, Noiles does not contemplate nor suggest a form cutter that could be inserted into the space between opposing vertebrae. Accordingly, the Applicants respectfully submit that Noiles does not anticipate or make obvious the invention of claim 1.

Furthermore, with respect to claims 2, 4, 5 and 7, these claims are believed likewise allowable at least by virtue of their dependency upon independent claim 1.

Claims 1, 5-7 and 13 have been rejected under 35 U.S.C. §102(b) as being anticipated by Frigg et al. (U.S. Patent No. 5,041,119). The Office Action asserts that Frigg et al. disclose a form cutter 1, a drive means 7 and a housing 4 that meets the elements of the rejected claims. The Applicants respectfully traverse this rejection for the following reasons.

Frigg et al. merely teach an angular attachment for a drill that is used in surgery. Specifically, Frigg et al teach a housing 4 having a front end 14 and a rear end 15 wherein the rear end 15 is open to receive the working end of a drilling machine 1. Thus, contrary to the assertions in the Office Action, reference number 1 denotes a drilling machine that drives the shaft 3, not a form cutter. The coupling shaft 3 is, in turn, attached to a drive shaft 7 of the frame that is connected to conical gears 9 and 10 which translate rotation from a vertical direction to a horizontal direction. Finally, a drill bit 10 is connected to the angular drill attachment for drilling holes for bone screws in the spinal column or pelvis (see column 2, lines 21 through 23).

In contrast, the present invention includes a form cutter having a profile capable of imparting a shape to the bone of opposing vertebral bodies that matches a

predetermined endoprosthesis surface shape. Frigg et al. does not teach or suggest that the drill bit 10 is used for imparting shape to a bone such that it matches with a predetermined endoprosthesis surface shape. Instead, all that is contemplated by Frigg et al. is merely drilling holes in bone for setting of bone screws. Thus, the Applicants respectfully submit that Frigg et al does not teach or suggest all the elements the claimed invention. Withdrawal of the rejection is respectfully requested, accordingly.

Furthermore, with respect to claims 5 through 7 and 13, these claims are believed to be allowable at least by virtue of their dependency upon claim 1.

Claim Rejections - 35 U.S.C. §103

Claim 14 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Noiles. The Office Action asserts that Noiles discloses the invention as claimed except for the device having a height of nine millimeters or less. To make up for the deficiencies of the reference, the Office Action asserts that it would have been obvious to one of ordinary skill in the art to make the Noiles device smaller in order to be able to use the device on very small animals. The Applicants respectfully traverse this rejection for the following reasons.

As discussed previously, Noiles teaches a fixation element for socket portions of an artificial ball and socket joint wherein a spherical reamer 42 is used to prepare a cavity in the pelvic bones. No teaching or suggestion is given by Noiles to reduce the size of either the fixation element 10 or the spherical reamer 42.

Furthermore, in order to establish a *prima facia* case of obviousness there must be a suggestion or motivation either in the reference itself or in the knowledge generally available to one of ordinary skill in the art to modify the reference. In the

present case, the stated motivation that it would have been obvious to modify Noiles "in order to be able to use the device on very small animals" has no basis in the teachings of the reference. Additionally, the Office Action provides no support or evidence that one of ordinary skill in the art would receive motivation to use a fixation element (specifically taught to be used for artificial joints in a human pelvis) at a reduced size for very small animals. Hence, this assertion is unsupported and, thus, inadequate for establishing a *prima facia* case of obviousness as required by the M.P.E.P. (see M.P.E.P. §2142 et seq.). Hence, the Applicants respectfully submit that the Office Action has not established a *prima facia* case of obviousness and request withdrawal of the rejection, accordingly.

Moreover, since claim 14 depends from claim 1, as discussed above, claim 14 is believed further allowable at least by virtue of its dependency.

Claims 8 through 12 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Frigg et al. The Office Action asserts that Frigg et al. disclose the invention as claimed except for a belt drive. However, these claims, dependent from claim 1, are believed allowable at least by virtue of their dependency.

Newly added claims 18 through 24 are believed to be allowable over the prior art of record. Specifically, none of the cited references teach or suggest a rotary form cutter having a profile matching a predetermined shape of an endoprosthesis wherein the rotary form cutter cuts an imparted shape into the surfaces of two opposing vertebral bodies that match the predetermined shape of the endoprosthesis as required in independent claim 18. Furthermore, none of the cited references, in particular, teaches or suggests a rotary form cutter having a rotation axis that is transverse to a longitudinal axis of an elongate housing in which it is housed as featured in claim 21.

Thus, for at least the above reasons, newly added claims 18 through 24 are believed allowable and the Applicants respectfully request that the application proceed to issuance.

Finally, with respect to the use of the term "milling" in the new title and also in the preambles of newly added claims 18-24, this word choice is not believed to add new matter. Specifically, both the specification and the previously presented claims teach a rotating cutter that forms a shape into a vertebral bone. This use of a rotary cutter for shaping bone can aptly be described as a milling process. In support, an accepted usage of the verb "mill" is defined in MerriamWebster's Collegiate Dictionary, Tenth Addition, 1996, as "to shape by means of a rotary cutter". Thus, the rotary cutter and process using this cutter already disclosed in the present application does indeed meet this accepted usage of the word "mill". Hence, one of ordinary skill in the art would recognize that the means and process described in the present application could be characterized as a milling operation and, therefore, the use of this word does not constitute new matter.

Allowable Subject Matter

The Applicants thank the Examiner for indicating that claims 15 through 17 are allowable over the prior art of record. In addition, claims 3 and 4 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form to include the limitations of the base claim and any intervening claims. The Applicants note that claim 4 was indicated as rejected under 35 U.S.C. §102(b) as being anticipated by Noiles. Thus, for purposes of this response, the Applicants assume that claim 4 stands rejected and is not merely objectionable. Nevertheless, claim 4 is believed to be allowable, as discussed previously, and claim

3 has not been rewritten at this time, pending reconsideration of the rejection of claim 1 by the Examiner.

In light of the foregoing comments, the Applicants urge that the application is in condition for allowance and request that the application proceed to issuance. If there are any outstanding issues remaining that could be resolved by an Examiner's Amendment or an interview, the Examiner is invited to contact the undersigned attorney in order to expedite prosecution of the application.

Respectfully submitted,

Todd S. Parkhurst (Reg). #26,494

Todd S. Parkhurst
Hill & Simpson
A Professional Corporation
85th Floor Sears Tower
Chicago, Illinois 60606
Telephone: 312-876-0200 - Ext. 3267
Attorneys for Applicants